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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,023	03/11/2004	Stefan Petersson	PN0103	6027
7590 Amersham Health, Inc. IP Department 101 Carnegie Center Princeton, NJ 08540				
EXAMINER LEACH, CRYSTAL I				
ART UNIT		PAPER NUMBER		
3737				
MAIL DATE		DELIVERY MODE		
10/16/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/798,023

## Applicant(s)

PETERSSON ET AL.

## Examiner

CRYSTAL I. LEACH

## Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1.5-11 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1.5-11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Paper No(s)/Mail Date \_\_\_\_\_
- 6) ☐ Other: \_\_\_\_\_

1. Applicant's arguments, see p. 6, filed August 6, 2008, with respect to the 35 U.S.C. 101 rejection of claim 14 has been fully considered and are persuasive. The 35 U.S.C. 101 rejection of claim 14 has been withdrawn.
2. Applicant's arguments with respect to claims 1, 5-11 and 13-15 have been considered but are moot in view of the new ground(s) of rejection.

### **DETAILED ACTION**

#### ***Information Disclosure Statement***

3. The Information Disclosure Statements (IDS) submitted on August 6, 2008 are in compliance with 37 CFR 1.97 and 1.98. The references therein have been considered.

#### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 16 recites the limitation "wherein step iii) is carried out after the agent has left the vascular bed" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. A vascular bed was never mentioned prior to this claim. Correct insufficiency by changing "the" to --a--.

#### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 5-11 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Golman et al. (6,574,495) or Ardenkjaer-Larson et al. (6,278,893) in view of Mugler, III et al. (5,245,282) or Held (6,310,478).

Golman et al. teach a method of magnetic resonance imaging of a sample, said method comprising: i) administering a hyperpolarised MR imaging agent in liquid phase comprising non- zero nuclear spin nuclei into the sample; ii) exposing the sample to a radiation at a frequency selected to excite nuclear spin transitions in said non-zero nuclear spin nuclei; iii) detecting MR signals from the sample and utilising spectral-spatial excitation; and iv) optionally generating an image, physiological data or metabolic data from said detected signals (see col. 2, l. 32-54; col. 3, l. 35-65; col. 4, l. 15-36; col. 5, l. 1-2; col. 5, l. 20-21; col. 5, l. 41-63; col. 9 – col. 10 col. 17, l. 28-44; col. 18, l. 8-16; col. 5, l. 20-21). Golman et al. further disclose the above method where the hyperpolarized agent includes from the group consisting of  $^1\text{H}$ ,  $^3\text{He}$ ,  $^3\text{Li}$ ,  $^{13}\text{C}$ ,  $^{15}\text{N}$ ,  $^{19}\text{F}$ ,  $^{29}\text{Si}$ ,  $^{31}\text{P}$  and  $^{129}\text{Xe}$  (see col. 3, l. 44 - col. 4, l. 2). Golman et al. also teach that it would be advantageous to use imaging sequences including, for example, EPI, RARE or FSE, but do not teach FISP or PSIF.

Ardenkjaer-Larson et al. teach a method of magnetic resonance imaging of a sample, said method comprising: i) administering a hyperpolarised MR imaging agent in liquid phase comprising non- zero nuclear spin nuclei into the sample; ii) exposing the sample to a radiation at a frequency selected to excite nuclear spin transitions in said non-zero nuclear spin nuclei; iii) detecting MR signals from the sample and utilising spectral-spatial excitation; and iv) optionally generating an image, physiological data or

metabolic data from said detected signals (see col. 2, l. 5-50; col. 2, l. 65 – col. 3, l. 29; col. 5, l. 11-29, 42-47, 53-64).

Golman et al. nor Ardenkjaer-Larson et al. teach detecting MR signals from the sample and utilising spectral-spatial excitation, in combination with a FISP or PSIF pulse sequence with a flip angle of 45 to 90 degrees.

Mugler, III et al. teach utilizing a FISP pulse sequence (see col. 1, l. 56- col. 3, l. 29; col. 7, l. 12-20; col. 8, l. 17-22). Mugler, III et al. do not explicitly teach that a flip angle of 45 to 90 degrees, However, it would be obvious to one of ordinary skill in the art to try various flip angles, including flip angles within the range of 45 to 90 degrees, in order to find the most efficient and/or effective flip angle producing the greatest quality image.

Held teaches utilizing a FISP pulse sequence with a flip angle of 45 to 90 degrees (see col. 3, l. 29-33).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include FISP or PSIF in the invention of either Golman et al. or Ardenkjaer-Larson et al., in light of the teachings of Mugler, III et al. or Held, in order to enhance the utility of the method and to employ a steady-state of the complete magnetization vector producing greater image quality.

### ***Conclusion***

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Driehuys et al. (US 2001/0000727) teach methods for imaging pulmonary and cardiac vasculature and evaluating blood flow using dissolved polarized

129 Xe; Spielman et al. (5,283,526) teach a method for performing single and multiple slice magnetic resonance spectroscopic imaging; Scmitt-Willich et al. (5,820,849) teach cascade polymer complexes, process for their production and pharmaceutical agents containing said complexes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRYSTAL I. LEACH whose telephone number is (571)272-5211. The examiner can normally be reached on Monday through Friday, 8 am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/  
Supervisory Patent Examiner, Art  
Unit 3737

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/Crystal I Leach/

Examiner, Art Unit 3737